# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY	)
LIMITED, TAKEDA PHARMACEUTICALS	)
NORTH AMERICA, INC., TAKEDA	?
PHARMACEUTICALS LLC, and TAKEDA	<b>?</b>
PHARMACEUTICALS AMERICA, INC.,	)
Plaintiffs,	) C.A. No. 08-339-SLR
v.	)
BARR LABORATORIES, INC., and BARR	)
PHARMACEUTICALS, INC.,	Ś
	í
Defendants.	Ś
	Ś
ETHYPHARM, S.A.,	Ś
, ,	)
Plaintiff,	Ś
•	)
v.	) C.A. No. 08-344-SLR
	)
BARR LABORATORIES, INC., and BARR	)
PHARMACEUTICALS, INC.,	)
	)
Defendants.	)

### STIPULATED PROTECTIVE ORDER

WHEREAS, the parties in these actions, plaintiffs Takeda Pharmaceutical
Company Limited ("Takeda Japan"), Takeda Pharmaceuticals North America, Inc., Takeda
Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively "Takeda North
America"), and Ethypharm, S.A. ("Ethypharm") and defendants Barr Laboratories, Inc. and Barr
Pharmaceuticals, Inc. (collectively "Barr"), believe, and the Court has determined, that good
cause exists for entry of this Order; and

WHEREAS, the parties have, through counsel, stipulated to entry of this Order ("Order") pursuant to Fed. R. Civ. P. 26(c) to prevent unnecessary disclosure or dissemination of confidential information of the parties, their affiliates or third parties; and

WHEREAS, the parties recognize that confidential information is being produced only for use in this civil action;

IT IS HEREBY ORDERED that the following provisions of this Order shall govern the confidential information produced by a party or its affiliates to any other party or by a third party to any party in the course of this civil action:

1. The term "Confidential Information" as used in this Order includes all documents, information, testimony or things produced during discovery which a party: (i) believes contain sensitive trade secrets, proprietary information, or other confidential information (including but not limited to non-public information concerning research, development, testing, or evaluation of pharmaceuticals, non-public patent applications and files, non-public manufacturing information, non-public license agreements or negotiations, non-public information concerning drug applications, and non-public communications with the Food and Drug Administration) that can be the subject of protection pursuant to Federal Rules of Civil Procedure 26(c); and (ii) designates as such in accordance with the procedures set forth in paragraph 6. Confidential Information may be contained in discovery information or materials produced or obtained in this action by or through any means and by or through any person or entity. The Confidential Information contained therein and all copies, recordings, abstracts, excerpts, analyses or other writings that contain, reveal or otherwise disclose such Confidential Information shall also be deemed Confidential Information.

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- 2. The parties will designate as "Confidential" all Confidential Information. The parties may designate as "Highly Confidential – Outside Attorneys' Eyes Only" all Confidential Information that satisfies the requirements of paragraph 1 and which comprises or contains particularly sensitive information of the parties and their affiliates, including, but not limited to, customer information, financial and marketing information, information relating to research, development and testing of a party's existing and proposed future products, information relating to the processes, apparatus, or analytical techniques used by a party in its present or proposed commercial production of such products, information relating to pending or abandoned patent applications which have not been made available to the public, and any other information as agreed to by the parties, that a disclosing party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the receiving party.
- 3. Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information shall be disclosed, disseminated and used by the Receiving Party only for purposes of this civil action. Except with the prior written consent of the Producing Party or upon prior order of this Court, Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information shall not be disclosed except in accordance with the terms, conditions, and restrictions of this Order.
- 4. The term "Producing Party" means the party or person designating documents or information as Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information under this Order.
- 5. The term "Receiving Party" shall mean the party to whom the Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information is disclosed.

- 6. The parties (or third parties producing documents or other evidence for use in this proceeding) may designate material as Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information in the following manner:
- (a) Depositions. When deposition testimony is or contains Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information, any attorney of record present may so designate that testimony by notifying others present on the record of the deposition. The deposition reporter shall then so mark the transcript that reports the testimony. The parties also may designate the entire deposition testimony of a witness as containing Confidential or Highly Confidential – Outside Attorneys' Eyes Only Information. Alternatively, a Producing Party may designate testimony or information disclosed at a deposition, including exhibits, that contain Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information by notifying all parties in writing, within thirty (30) days after the Producing Party's receipt of the transcript, of the specific pages and lines of the transcript that contain Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information. Each party shall attach a copy of such written statement to the face of the transcript and each copy thereof in its possession, custody or control. If no such designations are made either on the record at the time the deposition is taken or within the time period specified above, the transcript and exhibits shall not be deemed to contain Confidential or Highly Confidential-Outside Attorneys' Eyes Only Information. Accessibility to each transcript (and the information contained therein) of any deposition in its entirety shall be limited to outside counsel of record only, from the taking of the deposition until thirty (30) days after actual receipt of the transcript by the Producing Party, or until receipt of the notice referred to in this paragraph, whichever occurs sooner. At the expiration of the said thirty (30) day period, unless designations

in writing or at deposition are provided prior to the expiration of said period, the entire transcript shall be deemed non-confidential.

- (b) Confidential Information or Highly Confidential Outside

  Attorneys' Eyes Only Information contained in any affidavit, brief, memorandum or other paper

  filed with the Court in this action, or discovery request or response served on a party, may be

  designated as Confidential Information or Highly Confidential Outside Attorneys' Eyes Only

  Information by indicating on the face of such documents that one or more parties consider them

  to contain Confidential Information or Highly Confidential Outside Attorneys' Eyes Only

  Information.
- Information shall be designated by conspicuously affixing a legend in the form of "CONFIDENTIAL." Documents produced in discovery that contain Highly Confidential Outside Attorneys' Eyes Only Information shall be designated by conspicuously affixing a legend in the form of or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY." Documents that are produced for review and copying will be treated as Highly Confidential Outside Attorneys' Eyes Only for purposes of the review. The produced copies will bear the producing party's confidentiality legend as needed, and upon production the information will be treated as required by the affixed legend.
- 7. Except with the prior written consent of the Producing Party, or in accordance with the procedure set forth in paragraph 10, material designated "Confidential," and any summary, description or report containing such information, may be disclosed only to the following persons:

- (a) Outside counsel for the respective parties to this litigation and employees, contractors or vendors of said counsel who are assisting in the prosecution or defense of this litigation.
- legal/patent staff in connection with the prosecution or defense of this action, as well as paralegal assistants, stenographic and clerical employees working under the direct supervision of such individuals. With the exception of the in-house professionals designated by this subparagraph and identified by name below, persons involved in the research, development, or patenting, of any proton pump inhibitor product, including but not limited to management personnel involved in decision-making regarding the foregoing, are excluded from seeing Confidential Material. The designated in-house professionals, who may be substituted upon consent or showing of good cause, are:

For Takeda Japan: (1) Tadaaki Kitao, Coordinator, Intellectual Property

Department, Takeda Pharmaceutical Company Limited and (2) Atsuhiro Inaba, Assistant

Coordinator, Intellectual Property Department, Takeda Pharmaceutical Company Limited;

For Takeda North America: (1) George Kokkines, Associate General Counsel,
Litigation and Compliance, Takeda Pharmaceuticals North America, Inc., (2) Ken Greisman,
Senior Vice President, General Counsel, and Secretary, Takeda Pharmaceuticals North America,
Inc., (3) Mark Buonaiuto, Assistant Chief Legal Counsel, Patents and Trademarks, Takeda
Pharmaceuticals North America, Inc.

For Ethypharm:

For Barr: (1) Frederick J. Killion, Esq., Executive Vice-President and General Counsel, Barr Pharmaceuticals, Inc., (2) Heidi Kraus, Vice President Intellectual Property, Barr

Laboratories, Inc., and (3) Azeen R. James, Vice President Intellectual Property and Associate Counsel, Barr Laboratories, Inc.

- (c) Outside experts and consultants (and their employees or clerical assistants) who have been approved by the Producing Party according to paragraph 10 and who are employed, retained or otherwise consulted by outside counsel of record to assist in any way in the preparation and trial of this litigation. For purposes of this Order, the phrase "outside experts and consultants" shall not include any officer, director or employee of any party.
- (d) Court personnel in the conduct of their official duties and the trier of fact.
- (e) Persons or organizations expressly retained to assist or serve as translators, interpreters, copy services, court reporters, graphics and trial consultants, and document imaging and database consultants.
- (f) Any person who is indicated on the face of the document to be its originator or author or a recipient thereof; and
- (g) Any other person, either with the prior written consent of the Producing Party or pursuant to an order of the Court.
- 8. Except with the prior written consent of the Producing Party, or in accordance with the procedure set forth in paragraph 10, material designated "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY," and any summary, description or report containing such information, shall be limited to persons identified in subparagraphs 7(a), and 7(c)-(g).

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- 9. Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information may be used in the course of the trial of this action, subject to such restrictions as the court may find are reasonable to protect its confidentiality.
- 10. (a) A party may exclude from a deposition any person who is not entitled to have access to Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information when such Information is the subject of examination.
- (b) No Confidential Information shall be revealed or disclosed, in whole or in part, directly or indirectly, to any individual described in subparagraph 7(b), and no Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information shall be revealed or disclosed, in whole or in part, directly or indirectly, to any individual described in subparagraph 7(c), until that individual has been given a copy of this Order and has duly completed and signed an undertaking in the form attached hereto as Exhibit A. The original of each undertaking shall be retained, until the conclusion of this action including all appeals, by counsel for each party who intends to or does disclose to such individual any Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information.
- (c) Before disclosing Confidential Information or Highly Confidential Outside Attorneys' Eyes Only information to any person under subparagraph 7(c), the party seeking to make such disclosure shall first give written notice to counsel for the party whose Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information is to be disclosed (the Producing Party) of the name and address of the person to whom disclosure is to be made, including a current resume or curriculum vitae disclosing such person's prior or present relationship, if any, with the parties. If the Producing Party reasonably believes it would be harmed by the proposed disclosure, it may object in writing to such disclosure within ten (10)

business days after receipt of the notice. In the event of an objection, the parties shall promptly confer to attempt to resolve the concerns giving rise to the objection. If the parties are unable to reach agreement regarding such disclosure, the party seeking disclosure may, prior to the time of the intended disclosure, request this Court to issue an order permitting the disclosure. No disclosure shall be made until the expiration of the ten (10) business day period for the opposing party to make an objection, or if such objection is made, until the resolution of the objection, whether formally or informally.

(d) The disclosure of the identity of a consulting expert will not be a waiver of any privilege that applies to communications with the consultant or the consultant's work product. Furthermore, the parties agree that by stipulating to the entry of this Order, the parties do not intend to modify in any way the discovery rules applicable to consulting experts.

Outside Attorneys' Eyes Only Information shall constitute a representation that there is a valid basis for such designation. Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information shall be maintained by the Receiving Party under the overall supervision of outside counsel. The attorneys of record for the parties shall exercise best efforts to ensure that the information and documents governed by this Order are (i) used only for the purposes set forth herein, and (ii) disclosed only to authorized persons. Moreover, any person in possession of Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information shall exercise reasonably appropriate care with regard to the storage, custody or use of such Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information to ensure that the confidential nature of the same is maintained.

- 12. It is the intention of this Order that the following categories of information shall not be, and should therefore not be, designated as Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information: (a) any information that at the time of its disclosure in this action is part of the public domain by reason of prior publication or otherwise; (b) any information that after its disclosure in this action has become part of the public domain by reason of prior publication or otherwise through no act, omission or fault of the Receiving Party; (c) any information that at the time of its disclosure in this action is rightfully in the possession of the Receiving Party, its trial counsel or any expert retained by or for the Receiving Party; (d) any information that after its disclosure in this action is rightfully received by the Receiving Party, its trial counsel or any expert retained by or for the Receiving Party from a third party having the right to disclose such information; or (e) any information that was independently developed by the Receiving Party without the use of or reliance upon any designated material disclosed by the Producing Party. During the pendency of this action, any disputes as to whether information is Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information under the terms of this Order shall be resolved according to the procedure set forth in paragraph 13 hereof.
- 13. If a party disagrees with the designation of any information as Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information, such party shall first make its objection known to the Producing Party and request a change of designation. The parties shall first try to resolve such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court no sooner than five (5) days following the service of a written notice of disagreement. The burden of proving that information has been properly designated as

Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information is on the party making such designation. Until there is a determination by the Court, the information in issue shall be treated as Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information and subject to the terms of this Order. Any failure to object to any material being designated as Confidential Information or Highly Confidential -Outside Attorneys' Eyes Only Information shall not be construed as an admission by any nondesignating party that the material constitutes or contains a trade secret or other confidential information.

- 14. Confidential Material or Highly Confidential – Outside Attorneys' Eyes Only Information produced by a party may be disclosed to a 30(b)6) witness on behalf of, or any current employee of, that party in the course of his or her deposition in this action.
- 15. At the deposition of a third party, such third party may be shown documents designated as Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information if the document was authored by, sent or received by that third party, or provided that the Producing Party consents to such disclosure.
- 16. Nothing in this Protective Order shall preclude a Producing Party from disclosing to anyone or using in any way its own Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information.
- 17. Any person receiving Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information shall not disclose such information to any person who is not entitled to receive such information under this Order. If Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information is disclosed to any person not entitled to receive disclosure of such information under this Order, the person responsible for the

disclosure will inform counsel for the Producing Party and, without prejudice to other rights and remedies of any party, make a reasonable good faith effort to retrieve such material and to prevent further disclosure of it by the person who received such information.

18. Written material constituting or revealing Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information, when filed with the Court in this action for any reason, shall be filed in sealed envelopes or other appropriate sealed containers on which shall be endorsed the title of this action, an indication of the nature of the contents of such sealed envelope or other container, and a statement substantially in one of the following forms:

#### CONFIDENTIAL

#### FILED UNDER SEAL

-or-

# HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY FILED UNDER SEAL

- 19. The Clerk of the Court is directed to place and maintain under seal in accordance with this Order any such pleading or other document filed with or delivered to this Court pursuant to paragraph 18 or any other provision hereof.
- 20. Nothing herein shall prevent disclosure beyond the terms of this Order if the party producing Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders or permits such disclosure.
- 21. The inadvertent production in discovery of any privileged or otherwise protected or exempted information, as well as the inadvertent production in discovery of

information without an appropriate designation of confidentiality, shall not be deemed a waiver or impairment of any claim of privilege or protection, including but not limited to the attorney-client privilege, the protection afforded to work-product materials or the subject matter thereof, or the confidential nature of any such information, provided that the Producing Party shall promptly provide notice to the Receiving Party in writing when inadvertent production is discovered. Upon receiving written notice from the Producing Party that privileged information or work-product material has been inadvertently produced, such information shall be returned to counsel for the Producing Party and the Receiving Party shall not use such information for any purpose except application to the Court until further Order of the Court. In response to an application to the Court by the Receiving Party to compel production of such information, the Producing Party shall submit the documents or testimony at issue to the Court for in camera inspection.

- 22. Nothing herein shall prevent any party or non-party from seeking additional relief from the Court not specified in this Order, or from applying to the Court for further or additional Orders.
- 23. Third parties who produce information in this action may avail themselves of the provisions of this Order, and discovery materials produced by third parties shall be treated by the parties in conformance with this Order.
- 24. In the event that any of the parties (a) is subpoenaed in another action, (b) is served with a demand in another action to which it is a party, or (c) is served with any other legal process by a person not a party to this litigation, and is requested to produce or otherwise disclose discovery material that is designated as Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information by another party, the party subpoenaed or served in

accordance with this paragraph shall object to production of the Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information and shall give written notice to the Producing Party within five (5) business days. If the person seeking access to the Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information takes action against the party covered by this Order to enforce such a subpoena, demand or other legal process, it shall respond by setting forth the existence of this Order. Nothing in this Order shall be construed as precluding production of Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information covered by this Order in response to a lawful court order.

- 25. (a) Within sixty (60) days after filing of the final order in this action, all Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information shall be destroyed by all receiving parties or shall be returned to the Producing Party. If any Receiving Party destroys any such Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information, that party shall send a letter to the Producing Party confirming the same.
- (b) Notwithstanding the foregoing, outside counsel of record for each party may maintain in its files: its correspondence file of this case; its pleading file (including all briefs, memoranda, affidavits, and all papers served by/on the party represented); one copy of each document filed with the Court containing Confidential Information or Highly Confidential Outside Attorneys' Eyes Only Information; one copy of all depositions transcripts (and exhibits) and any notes or memoranda relating thereto; and all legal research memoranda. Nothing in this Confidentiality Order requires the return or destruction of attorney work product or attorney-client communications of any party that is maintained and stored by outside counsel in the

regular course of business. All of the above materials shall remain subject to the terms of this Order.

26. This Order shall remain in full force and effect until modified, superseded, or terminated by agreement of the parties or by an Order of the Court.

#### AGREED TO BY:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

By: /s/ Mary B. Graham

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-and-

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Attorneys for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

UNITED STATES DISTRICT HIDGE

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_\_, 2008.

#### **EXHIBIT A**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY	)
LIMITED, TAKEDA PHARMACEUTICALS	· (
NORTH AMERICA, INC., TAKEDA	)
PHARMACEUTICALS LLC, and TAKEDA	)
PHARMACEUTICALS AMERICA, INC.,	)
Plaintiffs,	) C.A. No. 08-339-SLR
v.	)
BARR LABORATORIES, INC., and BARR	)
PHARMACEUTICALS, INC.,	<b>`</b>
THE HOLD TO HOS, HIV.,	í
Defendants.	)
<del></del>	Ś
ETHYPHARM, S.A.,	)
Plaintiff,	)
<b>,</b>	Ś
v.	) C.A. No. 08-344-SLR
DANKARAN MARKARAN BARA	)
BARR LABORATORIES, INC., and BARR	)
PHARMACEUTICALS, INC.,	)
	· ·
Defendants.	)
I, , hereby declare that:	
<del></del>	

- I have carefully read and understand the foregoing Order (the "Order") of the United States District Court for the District of Delaware, in the above-captioned matter.
- I agree that I will be bound by and will comply with all of the provisions of this Order and I will make no disclosures of Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information to any person who is not permitted to have access to such Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information by this Order, as applicable.
- Upon final determination of this action, I will destroy all Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information received by me within sixty (60) days after sealing of the final order, or I will return such Confidential Information or Highly Confidential – Outside Attorneys' Eyes Only Information within sixty

- (60) days to the Producing Party. If I destroy such Confidential Information or Highly Confidential - Outside Attorneys' Eyes Only Information, I agree to send a letter to the Producing Party confirming the same.
- I understand that a violation of this undertaking is punishable as a contempt of court and hereby submit to the jurisdiction of this Court for the purpose of enforcement of this Order.
- I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Y	1
Executed	· nn·
LACCULCO	L VIII.

[signature]

[print or type name]

Title:

**Business Affiliation:** 

Address:

Phone: